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IS 11497 (1985): Catheter, Foley's, Rubber, for Prolonged Urinary Drainage [MHD 1: Surgical Instruments]

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(Reaffirmed 2001)

Indian Standard

SPECIFICATION FOR CATHETER, FOLEY'S, RUBBER, FOR PROLONGED URINARY DRAINAGE

1. Scope — *This standard prescribes dimensional and other requirements for Foley's catheter* used for prolonged urinary drainage.

2. Shape and Dimensions — As shown in Fig. 1, read with Table 1.

TABLE 1 CRITICAL DIMENSIONS AND BALLOON CAPACITIES OF FOLEY'S CATHETER

All dimensions in millimetres.

	*Catheter Size in Charriere Scale**								
	8	**10**	**12**	**14**	**16**	**18**	**20**	**22**	**24**
Length, (L)±5	350	350	450	450	450	450	450	450	450
Wall thickness (T)	0·3±·05	0·3±·05	1·0∓0·1	1·0±0·1	1·0±0·1	1·0±0·1	1·0±0·1	1·0±0·1	1·0±0·1
Balloon capacity, ml	5±0·5	50±·5	5∓0·5	30±1	30±1	30±1	30±1	30±1	30±1
B ± 0·5	5·0	5·5	6·0	6·5	7·0	7·5	8·5	9·0	9·5
C ± 0·5	7·5	8·0	8·5	9·0	9·5	10·0	11·0	11 5	12·0
D ± 0·5	4·5	5·0	5·5	6·0	6·5	7·5	8·0	8·5	9·0
E ± 1·0	15·0	15·0	15·0	30·0	30·0	30·0	30·0	30·0	30·0
F ± 0·5	3·0	3·0	3·0	6·0	6·0	6·0	6·0	6·0	6·0
G ± 0·3	1·5	1·5	1·5	3·0	3·0	3·0	3·0	3·0	3·0

*Charriere scale = 1 mm.

3. Material

3.1 Catheter shall be made from rubber latex conforming to IS : 5430-1981 'Specification for ammonia preserved concentrated natural rubber latex (*first revision*)', and compounded and vulcanized to meet the requirements of this specification.

3.1.1 The natural rubber shall be reasonably free from substances known to have deleterious action on rubber. The composition shall be free from irritants and have no known injurious effect on persons with whom it may come in contact. It shall not react with body fluids and urine.

3.2 A firm elastic thickened bluntly tapering cushion shall be provided at the tip.

3.3 A silicon coating may also be provided to the rubber in order to avoid urethral reactions.

3.4 Use of red rubber shall be avoided.

4. Workmanship and Finish

4.1 The catheter shall be homogeneous in composition, adequately vulcanized, evenly and smoothly finished and shall be free from pinholes, pits, cracks, crevices, grooves and other defects. The distal end of the eye shall have smooth finish and shall be entirely free from projections, grit and embedded particles.

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Adopted 27 December 1985

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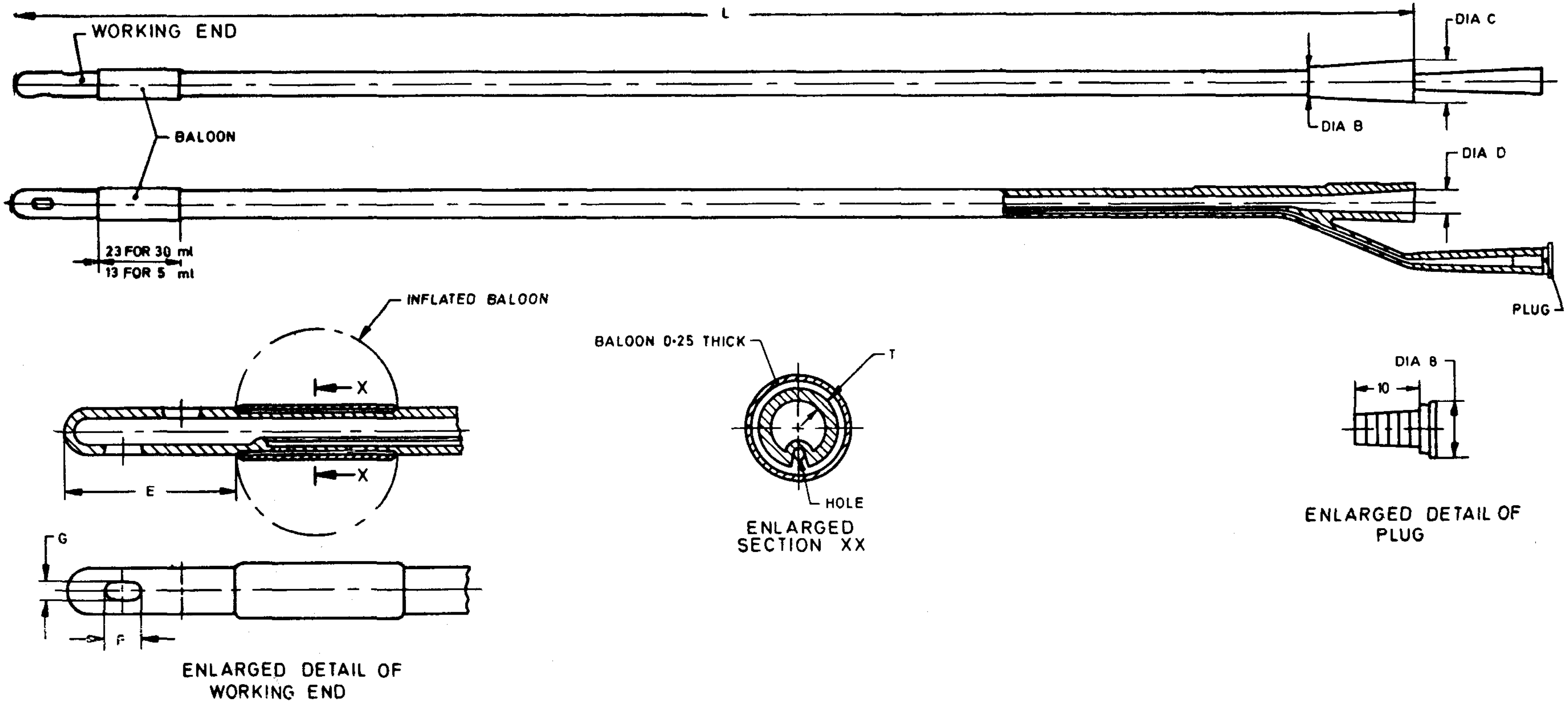

ENLARGED DETAIL OF WORKING END

ENLARGED SECTION XX

ENLARGED DETAIL OF PLUG

All dimensions in millimetres.

FIG. 1 CATHETER, FOLEY'S PATTERN

4.2 Balloon channel walls shall not stick together hampering inflation or deflation.

4.3 At the external broader end, the catheter shall be firmer, its wall resilient and thicker. This helps prevent collapse of wall during negative syringe suction to relieve blockade by gravel or blood clots.

4.4 Needle puncture shall be allowed into the side of the catheter (away from balloon channel) for tapping of urine specimen for culture, which may be often required. Elasticity of rubber shall allow such a puncture hole to seal off spontaneously when hypodermic needle is withdrawn.

4.5 There shall be colour coding marking on outer end of side (balloon) tube of catheter to identify size at a glance. The 30 ml balloon shall represent an average inflation capacity but allow for 20 ml extra water inflation without breaking. Similarly, 5 ml balloon shall allow for a total of 10 ml inflation.

4.6 Balloon catheter joint shall be incorporated within catheter substance so as not to affect outside smoothness of catheter and also to permit strengthening effect on balloon wall upon inflation.

4.7 The body of catheter shall be firm, elastic, resilient, able to withstand continuous traction of 1 kg without undue permanent lengthening effect produced after such use for 3 weeks.

4.8 The catheter side lumen tube leading to the balloon shall have a teat like thickening at its end away from balloon with depression in it adapted to take in a nozzle of 10 or 50 ml glass syringe.

4.9 A non-return valve mechanism shall be provided to ensure that only if a syringe nozzle is reapplied firmly against the teat in the above manner, fluid flows back into the barrel resulting in deflation of balloon for catheter removal.

5. Requirements

5.1 *Physical Requirements* — The physical requirements of rubber used for catheters shall be as given in Table 2.

TABLE 2 PHYSICAL REQUIREMENTS OF RUBBER USED FOR CATHETERS

Sl No.	Characteristic	Value Before Ageing	Maximum Change From the Original Value After Accelerated Ageing at 70±1°C for 168 Hours in Air Oven
(1)	(2)	(3)	(4)
i)	Tensile strength, MN/m^2 (kgf/cm^2), *Min*	10 (100, approx)	$\left.\begin{array}{l}+10\\-25\end{array}\right\}$ percent
ii)	Elongation at break, percent, *Min*	400	$\left.\begin{array}{l}+0\\-25\end{array}\right\}$ percent
iii)	Percent elongation under a tensile stress of 2 800 kN/m^2 (28 kgf/cm^2 approx) of original area of cross-section of test piece	Between 100 and 250	—
iv)	Tension set (at 200 percent elongation), percent, *Max*	10	—
v)	*p*H of water extract	7±0·5 (*see* Appendix A)	—
vi)	Extractable colour	No colour or precipitate shall be formed but faint turbidity (to the extent of slight translucence) may be permitted (*see* Appendix B)	—

5.1.1 The catheter shall be free from harmful contamination of heavy metals, arsenic, copper and manganese. The concentration of the metal impurities shall not exceed 5 ppm in the sterile pyrogen-free isotonic saline solution as prescribed in Appendix C.

5.2 *Resistance to Ageing Under Tension* — Tubing cut from the catheter when subjected to accelerated ageing under tension as prescribed in **5.3.1** shall not show any signs of cracking or other evidence of failure of the stretched part.

5.2.1 Cut end of a piece of tubing of the catheter shall be fitted over a glass tube of external diameter 40 to 50 percent greater than the internal diameter of the rubber tubing and the hole subjected to accelerated ageing for 168 hours at 70±1°C. There shall be no deterioration in its condition after the test.

5.3 *Hydraulic Test* — The catheter shall withstand the internal hydraulic pressure of 70 kN/m^2 (0·7 kgf/cm^2 approx) above atmoshpheric pressure without leakage, when tested according to **11** of IS : 443-1975 'Methods of sampling and test for rubber hoses (*second revision*)'.

6. Marking — Each catheter shall be legibly and indelibly marked with the manufacturer's name or recognized trade-mark, if any, and the year of manufacture together with the size number and balloon capacity.

6.1 The package shall also be marked legibly and indelibly with the name or trade-mark of the manufacturer, lot and serial number of the package, size number of the catheter, month and year of manufacture, and number of catheters in the package.

6.2 *ISI Certification Marking* — Details available with the Indian Standards Institution.

7. Packing — Each catheter shall be packed in a bag leakproof for sterilization. Ten such bags shall be packed in a bag which is leakproof for sterilization purpose. The bags may then be packed in cartons.

8. Sterilization — The cartons containing the catheters shall be sterilized by radiation sterilization in accordance with the procedures given in IS : 10150-1981 'Guide for sterilization of medical products'. Suitable indicators shall be affixed to each pack for indication of the sterility.

9. Sampling — Sampling procedure and acceptance criteria for the instruments shall be as agreed to between the purchaser and the supplier. However, a recommended scheme for the same is given in Appendix D.

APPENDIX A

(*Clause* 5.1)

DETERMINATION OF *p*H OF WATER EXTRACT

A-1. Procedure — Cut 5 catheters into 2-mm pieces. Autoclave the pieces for 5 minutes at a pressure of 40 to 50 kN/m^2 (approx 0·4 to 0 5 kgf/cm^2) with 200 ml of water. Discard the first extract and repeat the process with another 500 ml of water for 40 minutes. Decant the extract, cool and determine the *p*H with a *p*H meter.

APPENDIX B

(*Clause* 5.1)

TEST FOR EXTRACTABLE COLOUR

B-1. Procedure — Cut 5 catheters into 10-mm pieces and mix them. Weigh about 20 g of these pieces. Autoclave them with 100 ml of water under a steam pressure of 100 of 135 kN/m^2 (approx 1·0 to 1·35 kgf/cm^2) at a temperature of 120 to 125°C for 30 minutes. Cool and examine the extracted solution.

APPENDIX C

(*Clause* 5.1.1)

TEST FOR HEAVY METALS

C-0. Outline of the Method

C-0.1 The solution is prepared as in **C-0.2** and tested with aqueous hydrogen sulphide solution. The resultant brown colour, if any, is matched with that produced with a standard lead solution.

C-0.2 *Preparation of Test Solution* — Pass 40 ml portions of sterile pyrogen-free isotonic saline solution containing 9 g of sodium chloride per litre at room temperature through the catheter at a flow rate of approximately 10 ml per minute and collect the effluent. Make up the solution to 250 ml.

C-1. Apparatus

C-1.1 *Nessler Cylinders* — 100 ml capacity (*see* IS : 4161-1967 Specification for nessler cylinders).

C-2. Reagents

C-2.1 *Citric Acid*

C-2.2 *Concentrated Nitric Acid* — *See* IS: 264-1976 'Specification for nitric acid (*second revision*)'.

C-2.3 *Bromophenol Blue Indicator* — Dissolve 0·1 g of bromophenol blue in 100 ml of rectified spirit conforming to IS : 323-1959 Specification for rectified spirit (*revised*).

C-2.4 *Copper Sulphate*

C-2.5 *Hydrogen Sulphide Gas* — From Kipp's apparatus.

C-2.6 *Dilute Nitric Acid* — Approximately 1 percent.

C-2.7 *Ammonium Hydroxide* — Dilute 1 volume of liquor ammonia (RD 0·92) with 10 volumes of water.

C-2.8 *Thymol Blue Indicator* — Dissolve 0·1 g of thymol blue in 100 ml of rectified spirit conforming to IS : 323-1959.

C-2.9 *Potassium Cyanide Solution* — 10 percent(m/v).

C-2.10 *Hydrogen Sulphide Solution* — Freshly prepared saturated solution.

C-2.11 *Standard Lead Solution* — Dissolve 0·800 g of lead nitrate in water and make up the solution to exactly 1 000 ml. Pipette out 10 ml of the solution and dilute it again with water to 1 000 ml. One millilitre of the final solution contains 0·500 mg of lead (Pb). The solution shall be freshly prepared.

C-3. Procedure

C-3.1 Prepare a solution as in **C-0.2** but make up the volume to 100 ml. Transfer the solution to a beaker. Add 5 g of citric acid and adjust *p*H from 3·0 to 3·4 by adding ammonium hydroxide to give a yellowish purple colour with bromophenol blue indicator. Add about 5 g of copper sulphate to act as co-precipitant. Precipitate sulphides by passing hydrogen sulphide until solution is saturated. Dissolve the sulphides, without previous washing, with 5 ml of hot dilute nitric acid, drawing solution through filter into the original flask; wash with hot water, and collect the washing along with the solution in nitric acid. Boil to remove sulphuretted hydrogen. Concentrate the content to about 75 ml. Add 3 to 4 g of concentrated nitric acid previously dissolved in water, make ammoniacal to bring *p*H between 8·5 and 10 (bluish-green to blue towards drop of thymol blue indicator) and add 5 ml of potassium cyanide solution. Transfer to a Nessler cylinder, add 10 ml of hydrogen sulphide solution, dilute to the mark and shake. Carry out a control test using 1 ml of standard lead solution and the same quantities of other reagents as used in test with the material.

C-3.2 The test solution shall be taken as not having exceeded the limit prescribed if the intensity of colour produced in the test with the material is not greater than that produced in the control test.

APPENDIX D

(*Clause* 9)

SAMPLING PLAN AND CRITERIA FOR CONFORMITY

D-1. Lot — In a consignment, all the catheters of the same size number, manufactured from the same material under similar conditions shall be grouped together to constitute a lot.

D-2. Scale of Sampling

D-2.1 Each lot shall be tested separately for the requirements of this specification.

D-2.2 The number of catheters to be sampled from each lot for examining the requirements of shape and dimensions, material and workmanship and finish shall be in accordance with Table 3. These samples shall be selected at random with the use of random number tables (*see* IS : 4905-1968 Methods for random sampling).

TABLE 3 SCALE OF SAMPLING FOR CATHETERS

Lot Size (1)	Sample Size for Testing the Requirements of Clauses 2,3 and 4 (2)
Up to 25	5
26 ,, 50	8
51 ,, 150	13
151 ,, 300	20
301 and above	32

D-3. Number of Tests and Criteria for Conformity

D-3.1 When the catheters are packed in cartons, at least two cartons shall be opened for selecting the required number of items. After sampling, the cartons as well as the bags shall be re-packed in accordance with the requirements given in **7** and **8** of this standard.

D-3.2 Each catheter selected according to Table 3 shall be examined for the shape and dimensions, material and workmanship and finish. Any catheter failing in one or more of these requirements shall be considered to be defective. No defective catheter shall be permitted if the lot is to be deemed acceptable under this clause.

D-3.3 The lot which has been found satisfactory under **D-3.2** shall then be tested for other requirements. For this purpose, three samples shall be drawn for hydraulic test, one for physical requirements and one for resistance to ageing under tension. If found suitable, the samples already used for one test may be used for other test also. All the samples tested for various characteristics shall meet the corresponding requirements if the lot is to be accepted under this clause.

EXPLANATORY NOTE

In the preparation of this standard, assistance has been derived from IND/GS/NED/507 'Specification for Foley's catheter', issued by the Ministry of Defence, Government of India.

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